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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

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**Food and Drug Administration**

**[Docket No. 99D–2638]**

# Extra-Label Use of Medicated Feeds for Minor Species; Compliance Policy Guide; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a new compliance policy guide (CPG) section 615.115 entitled "Extra-Label Use of Medicated Feeds for Minor Species." The purpose of this CPG is to provide guidance to FDA personnel concerning the agency's exercise of regulatory discretion with regard to the extra-label use of medicated feeds for minor species. This CPG has been revised in response to comments received on the draft.

**DATES:** Submit written comments at any time.

**ADDRESSES:** Submit written requests for single copies of the CPG to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the CPG to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the full title of the CPG and the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for the electronic access to the CPG section 615.115 entitled "Extra-Label Use of Medicated Feeds for Minor Species."



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**FOR FURTHER INFORMATION CONTACT:** Frances M. Pell, Center for Veterinary Medicine (HFV–235), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0188, e-mail: fpell@cvm.fda.gov.

**SUPPLEMENTARY INFORMATION:**

## I. Background

In the **Federal Register** of August 25, 1999 (64 FR 46400), FDA published a notice of availability of a draft CPG entitled "Use of Medicated Feeds for Minor Species." This CPG was issued as a level 1 draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September, 2000). The purpose of this CPG is to provide guidance to FDA staff concerning the agency's exercise of regulatory discretion with regard to the extra-label use of medicated feeds for minor species. The CPG represents the agency's current thinking on this subject. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

The agency received comments regarding this CPG and has revised the CPG in response to the comments. Following is a discussion of the issues raised by the comments.

## II. The Final Guidance

The agency received 21 comments on the draft CPG. When finalizing the CPG, the agency considered the comments and, as appropriate, incorporated them into the final guidance. The final version of the CPG differs from the draft only in three areas. The first is a change in the minor species definition to reflect a corresponding change to the new animal drug regulations at 21 CFR 514.1. Sheep are now considered a minor species for all data collection purposes (see 65 FR 47668, August 3, 2000).

The second change is a minor clarification of existing provisions. The medicated feed must be manufactured and labeled in accordance with the approved conditions of use. This means that the feed cannot be reformulated in dosage, in form, or nutritional content such that it would no

longer be appropriate as a feed for the species for which it is approved. For example, a medicated feed approved for chickens may not be pelleted for use in laboratory animals. An approved swine medicated feed may not be made to correspond to the nutrient requirements of pheasants or deer. All labeling must be truthful and in accordance with the approved conditions of use.

The third change is further clarification of limitations on the agency's intent to exercise regulatory discretion with regard to extra-label use of medicated feeds. If the medicated feed is to be used in a food-producing minor species, the product must be approved in a food-producing major species. The agency intends to exercise regulatory discretion only for farmed or confined species not for unconfined wildlife. In aquaculture, the agency intends to exercise regulatory discretion only for extra-label use of medicated feeds already approved for an aquatic use because factors in the aquatic environment that may affect the safety and/or effectiveness of the medicated feed are so varied.

## III. Availability of Medicated Feeds for Minor Species

FDA plans to continue to address the issue of lack of availability of medicated feeds for minor species. There are serious shortcomings in the legal availability of medicated feeds for minor species. These include the need for specially formulated feeds for laboratory and zoo animals and the needs of species raised in aquaculture. Future guidance will be directed specifically at these needs.

## IV. Electronic Access

Persons with access to the Internet may obtain the CPG at http://www.fda.gov/cvm and http://www.fda.gov/ora.

## V. Comments

As with all of FDA's guidances, the public is encouraged to submit written comments with new data or other new information pertinent to this CPG. FDA will periodically review the comments and, where appropriate, the CPG will be amended. The public will be notified of any such amendments through a notice in the **Federal Register**.

Dated: 4-18-01
April 18, 2001.

Dennis E. Baker,
Associate Commissioner for Regulatory Affairs.

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